

Applicant: P. Bonutti  
Application No.: 10/685,117  
Examiner: G. Jackson

### Remarks

Claims 4-33 are presented for the Examiner's review and consideration. Claims 4, 8, 11, and 13 have been amended, and claims 1-3 have been canceled.

### Double Patenting Rejection

Claims 1-33 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,238,395. In response and in order to expedite the prosecution of this application, Applicant submits herewith a Terminal Disclaimer to obviate the double patenting rejection. It should be understood that the Terminal Disclaimer is being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimer is necessary.

### 35 U.S.C. §102 Rejections

Claims 1-3, 13-16, and 21 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,219,359 to McQuilkin *et al.* (hereinafter "McQuilkin"). Also, claims 1 and 2 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,823,794 to Pierce (hereinafter "Pierce"). In response, Applicant respectfully submits that these rejections should be withdrawn.

McQuilkin discloses a suture apparatus wherein an elongate length of suture is passed through holes in a first small plate/pledget and holes in a second small plate/pledget. The suture is then tied to retain the two small plates relative to each other and to retain in use tissue between the two small plates/pledgets (abstract).

Pierce discloses a surgical pledget including a suture entrance slit extending through the pledget from a side wall to a central suture location within the pledget and means for retaining the suture at the suture location so that the pledget may be positioned on a medial portion of a suture (abstract).

In contrast, Applicant discloses, *inter alia*, bone suture assemblies for treating a fractured bone (abstract). In the embodiment of the invention illustrated in FIG. 10, a pair of bone plates and rigid fasteners are used in association with a bone suture assembly (¶0128). A first suture

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anchor is pressed against the plate member by tension in a suture. The suture extends through a passage in the bone. A second anchor is pressed against the plate member by the tension in the suture (¶0131).

Applicant respectfully contends that the present invention is not taught or suggested by McQuilkin or Pierce, alone or in combination. Initially, Applicant contends that the cited references do not teach a fracture fixation device. McQuilkin and Pierce teach the use of pledgets and a suture to retain tissue. Neither reference discloses or suggests a suture to be positioned through a fracture of a bone or pledgets for compressing the fracture together. Applicant, on the other hand, specifically teaches a device for repairing and stabilizing a fractured bone. Applicant's suture and retaining members compress together portions of bone on opposite sides of a fracture. Applicant's bone fracture fixation device enhances the healing environment of the bone.

Furthermore, as seen in the embodiment of Figure 10 and explained in the specification, Applicant positions a bone plate between a suture anchor and the bone. A suture is tensioned to secure the bone plate relative to the bone. McQuilkin and Pierce, on the other hand, position their pledgets directly against tissue. Neither McQuilkin nor Pierce teach or suggest positioning a bone plate between the pledget and tissue.

Applicant has amended independent claim 13 to include, *inter alia*, that the first bone plate and first suture anchor are positioned generally on the same side of the bone. Accordingly, Applicant respectfully submits that claim 13 is patentably distinct over McQuilkin and Pierce. Based on at least their dependencies, Applicant also submits that claims 14-16 and 21 are allowable as well. In order to expedite prosecution, Applicant has canceled claims 1-3. It should be understood that the cancellation of these claims should not be construed as an admission that claims 1-3 are unpatentable over the cited references.

### 35 U.S.C. §103 Rejection

Claims 8-12 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,366,480 to Corriveau *et al.* (hereinafter "Corriveau") in view of McQuilkin or Pierce. In response, Applicant respectfully submits that this rejection should be withdrawn.

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Corriveau discloses a buttressing pledget manufactured from synthetic elastomeric material (abstract). The surgical buttressing pledgets used in this invention are made from injection molded silicone materials (col. 3, lines 21-22). Referring to FIGS. 1 and 5, the molded or extruded buttressing pledget is rectangular in shape (col. 3, lines 63-64). Referring to FIGS. 6A and 6B, the molded or extrude buttressing pledget is tubular in shape (col. 4, lines 10-11).

Applicant respectfully contends that Corriveau, alone or in combination with McQuilkin and/or Pierce, fails to teach or suggest the present invention. Corriveau, like McQuilkin and Pierce, discloses pledgets for retaining tissue. As previously stated, McQuilkin and Pierce fail to disclose a device for the repair of a fractured bone. Applicant contends that Corriveau does not remedy this deficiency, i.e., Corriveau does not teach a bone fracture fixation device.

Furthermore, Applicant positions a tubular member through the fractured bone and places a suture through the tubular member. The ends of the suture are secured with at least one suture anchor. Applicant concedes that Corriveau teaches a tubular member, but that tubular member is a pledget. Corriveau's pledgets are placed against a tissue mass not within the tissue mass. Furthermore, Corriveau, McQuilkin, and Pierce, either alone or in any combination do not teach or suggest the use of both a tubular member placed in tissue and a bone plate.

Applicant has amended claim 8 to include, *inter alia*, a tubular member positioned through a fractured bone generally orthogonal to the first bone plate. Accordingly, Applicant respectfully submits that claim 8 is patentable over the cited references. Based on at least their dependencies, Applicant submits that claims 9-12 and 22 are allowable as well.

### Conclusion

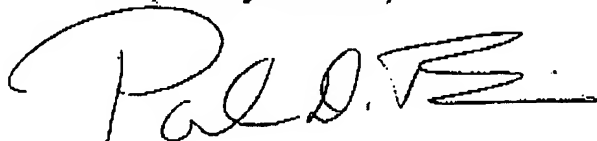
In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$100.00 for one additional independent claim and a fee of \$55 for a terminal disclaimer are believed to be due with this submission. The required fees are being paid via

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Credit Card. Please charge any additional, required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 782-A03-009-3).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco". The signature is fluid and cursive, with a large initial "P" and a stylized "B" at the end.

Paul D. Bianco, Reg. # 43,500

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Enclosures